

REMARKS

Claims 1-9 and 11-40 are pending in the present application.

At the outset, Applicants wish to thank the Examiner for the indication that the election of species requirement for Claim 31 has been withdrawn (paper number 16, page 2, paragraph number 1). Reconsideration of the outstanding grounds of rejection is requested.

The rejection of Claims 31-40 under 35 U.S.C. §101 is traversed.

The Examiner has rejected the Claims 31-40 as being drawn to non-statutory subject matter. It is the Examiner's opinion that the claims do not distinguish over naturally occurring *products* (paper number 16, page 2, paragraph number 4). However, Applicants note that Claims 31-40 are method (*i.e.*, process) claims and, therefore, do not read on products. Clearly the Examiner must recognize that a method (*i.e.*, process) necessarily requires the "hand of man." Moreover, recognition and statutory support for the requirement of the patentability of a method (*i.e.*, process), and therefore the necessity of the "hand of man," is provided by the text of 35 U.S.C. §101 (reproduced for the Examiner's convenience).

35 U.S.C. §101 Inventions patentable.

Whoever invents or discovers any new and useful *process*, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title. (*emphasis added*)

In recognition of the patentability of method claims, the Office routinely grants patents in virtually every field of endeavor from business methods to biotechnology. Therefore, as in these fields of endeavor, Applicants submit that the claimed invention is in full compliance

with 35 U.S.C. §101. Therefore, this rejection is without merit and should be withdrawn. Acknowledgement to this effect is solicited.

The rejection of Claims 31-40 under 35 U.S.C. §112, first paragraph (“written description”) is traversed.

The Office has alleged that the specification fails to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (paper number 16, page 4, lines paragraph 6). It appears that this ground of rejection is based on the absence of a description of multiple “representative microorganisms reciting the desired properties of deficiency in any repressor of any sequence/structure of any enzyme/protein involved in L-methionine biosynthesis and enhanced activity of any homoserine transsuccinylase of any sequence/structure made by any genetic modification.” (paper number 16, page 3, paragraph 6).

Applicants remind the Examiner that MPEP §2163.02:

An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

The Examiner’s attention is directed to the description at page 10, line 19 to page 16, line 6 (and references cited therein) where Applicants provide painstaking detail of the repressor of L-methionine biosynthesis system. Further, the Examiner’s attention is directed to the description at page 16, line 8 to page 20, line 7 (and references cited therein), which provides extensive detail to describe the homoserine transsuccinylase of the present invention. Moreover, at page 20, line 9 to page 22, line 20 (and references cited therein) the

S-adenosylmethionine synthetase is fully described, at page 22, line 22 to page 23, line 27 (and references cited therein) the artisan can find a description of L-threonine auxotrophy, and at page 24, line 1 to page 25, line 11 (and references cited therein) Applicants disclose production of L-methionine. A further understanding of the full scope of the present invention and the description thereof is provided in the "Best Mode for Carrying out the Invention" (page 25, line 19 to page 45, line 15).

In view of the foregoing, Applicants submit that the specification provides an adequate description to allow the skilled artisan to recognize what has been invented and what is claimed is adequately described in the specification within the meaning of 35 U.S.C. §112, first paragraph.

Accordingly, withdrawal of this ground of rejection is requested.

The rejection of Claims 31-40 under 35 U.S.C. §112, first paragraph ("enablement") is traversed.

The Office has taken the position that the claimed invention is not supported by an enabling disclosure (paper number 16, page 4, paragraph 7). Applicants respectfully disagree.

MPEP §2164.04 states:

In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)

With respect to Claims 31-40, Applicants note that the Examiner has not provided reason and/or explanation to establish a reasonable basis to question the enablement of the claimed invention. In paper number 16, page 4, paragraph 7, the Examiner has merely provided a collection of conclusory statements without any supporting evidence or scientifically

reasonable analysis. Accordingly, the rejection of Claims 31-40 under 35 U.S.C. §112, first paragraph, is not tenable and must be withdrawn.

The basis for determining compliance with the enablement requirement is set for in MPEP §2164.04, which states:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In the present specification, Applicants provide a detailed explanation of how the skilled artisan may identify, clone, express, and characterize any polynucleotides necessary to practice the present invention, including repressors and means to selectively enhance production of the appropriate polynucleotides. Moreover, the present specification also fully describes suitable bacteria and auxotrophs thereof, including culturing conditions for the same.

Specifically, the Examiner's attention is directed to the description at page 10, line 19 to page 16, line 6 (and references cited therein) where Applicants provide painstaking detail of the repressor of L-methionine biosynthesis system. Further, the Examiner's attention is directed to the description at page 16, line 8 to page 20, line 7 (and references cited therein), which provides extensive detail to describe the homoserine transsuccinylase of the present invention. Moreover, at page 20, line 9 to page 22, line 20 (and references cited therein) the S-adenosylmethionine synthetase is fully described, at page 22, line 22 to page 23, line 27 (and references cited therein) the artisan can find a description of L-threonine auxotrophy, and at page 24, line 1 to page 25, line 11 (and references cited therein) Applicants disclose production of L-methionine. A further understanding of the full scope of the present invention and the

description thereof is provided in the "Best Mode for Carrying out the Invention" (page 25, line 19 to page 45, line 15).

MPEP §2164.01 states:

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

In view of the foregoing highlighted sections of the specification, Applicants submit that the skilled artisan would be able to readily make or use the claimed invention even in the absence of extrinsic references. Nonetheless, Applicants **submit herewith** the following 5 references that evidence the fact that amino acid sequences for repressors and homoserine transsuccinylase were known in the art at the time of the present invention:

- 1) Urbanowski, et al., *J. Bacteriol.*, 165(3):740-745 (1986);
- 2) Mares, et al., *J. Bacteriol.*, 174(2):390-397 (1992);
- 3) Yocum, et al., *J. Bacteriol.*, 178(15): 4604-4610 (1996);
- 4) Omori, et al., *J. Bacteriol.*, 175(3): 785-794 (1993); and
- 5) Urbanowski, et al., *Gene*, 35: 187-197 (1985).

Therefore, when the disclosure of the present invention is combined with the knowledge generally available in the art at the time of the present invention, it would require nothing more than routine skill to practice the full scope of the present invention. As such, Applicants submit that the claims of the present application are fully enabled within the context of 35 U.S.C. §112, first paragraph.

Based on the foregoing, Applicants submit that the present claims are fully enabled by the specification and the common knowledge available in the art and as such withdrawal of this ground of rejection is requested.

The rejection of Claims 37-39 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Applicants wish to thank the Examiner for bringing this matter to their attention, as well as providing a recommendation to correct the same. Consistent with the Examiner's suggestion, Claims 37-39 have been amended to depend from Claim 33. Accordingly, this ground of rejection is now believed to be moot.

Applicants request acknowledgment that this ground of rejection has been withdrawn.

Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

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